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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,691	03/08/2004	Marc Bellotti	44378/293531 (13131-0331)	6082

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,691	BELLOTTI ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, drawn to a particle derivative of at least one form of high density lipoprotein comprising apolipoprotein A-1 and phospholipids, classified in class 530, subclass 359.

II. Claims 25-29 drawn to a particle derivative of pre-beta form of high density lipoprotein comprising a protein shell and a lipid bi-layer substantially devoid of cholesterol wherein the particle derivative is discoidal in shape, classified in class 530, subclass 359.

III. Claims 30-48, drawn to a method for making a particle derivative of at least one form of high density lipoprotein wherein the particle derivative comprises a protein shell and a lipid bi-layer, classified in class 435, subclass 69.1.

IV. Claims 49-50 and 59-62 drawn to a method for modifying at least one form of high density lipoprotein contained in plasma serum or other suitable blood fraction of a patient, classified in class 514, subclass 12.

V. Claims 51-52, drawn to a method of modifying a protein distribution in a fluid wherein the protein distribution has a first state having alpha high density lipoproteins and pre-beta high density lipoproteins, classified in class 514, subclass 12.

VI. Claims 53-54, drawn to a method of enhancing an ABCA 1 pathway of a patient with a first protein distribution, classified in class 514, subclass 12.

VII. Claims 55-58, drawn to a method of modifying a protein distribution in a fluid wherein the protein distribution has a first state, the first state having more alpha high density lipoprotein than pre-beta high density lipoprotein, classified in class 514, subclass 12.

VIII. Claims 63-64, drawn to a kit comprising high-density lipoprotein source container, classified in class 530, subclass 359.

IX. Claims 65-66, drawn to a method for enhancing cellular cholesterol efflux comprising administration of a modified HDL particle to patient, classified in class 514, subclass 12.

X. Claims 67-68, drawn to a particle comprising a modified HDL particle, wherein the modified HDL particle has relatively normal complement of Apo A-1 and substantially reduced cholesterol and phospholipid compared to an HDL particle before modification, classified in class 530, subclass 539.

XI. Claims 69-71, drawn to a biological fluid capable of enhancing an ABCA1 of a patient wherein said biological fluid is made by modifying a fluid having a first concentration of pre-beta high density lipoprotein relative to total protein, classified in class 530, subclass 539.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and (II, VIII, X-XI), II and (VIII, X-XI), VIII and (X-XI), X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The product of the invention of Group I is a particle derivative of at least one form of high density lipoprotein comprising apolipoprotein A-1 and phospholipids, the product of the invention of Group II is a particle derivative of pre-beta form of high density lipoprotein comprising a protein shell and a lipid bi-layer substantially devoid of cholesterol wherein the particle derivative is discoidal in shape, the product of invention of Group VIII is a kit comprising high density lipoprotein source container, the product of the invention of Group X is a particle comprising a modified HDL particle, wherein the modified HDL particle has relatively normal complement of Apo A-1 and substantially reduced cholesterol and phospholipid compared to an HDL particle before modification, the product of the invention of Group XI is a biological fluid capable of enhancing an ABCA1 of a patient wherein said biological fluid is made by modifying a fluid having a first concentration of pre-beta high density lipoprotein relative to total protein.

Inventions III and (I-II, VIII, X-XI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different

process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another materially different process such as the method of chemical synthesis.

Inventions (I-II, VIII, X-XI) and (IV-VII, IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as the process of making Anti-bodies.

Inventions IV and (IV-VII, IX), V and (VI-VII, IX), VI and (VII, IX), VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. The product of the invention of Group IV is a method for modifying at least one form of high density lipoprotein contained in plasma serum or other suitable blood fraction of a patient, the product of the invention of Group V is a method of modifying a protein distribution in a fluid wherein the protein distribution has a first state having alpha high density lipoproteins and pre-beta high density lipoproteins, the product of the invention of Group VI is a method of enhancing an ABCA 1 pathway of a patient with a first protein distribution, the product of the invention of Group VII is a method of modifying a protein distribution in a fluid wherein the protein distribution has a first state, the first

state having more alpha high density lipoprotein than pre-beta high density lipoprotein, the product of the invention of Group IX is a method for enhancing cellular cholesterol efflux comprising administration of a modified HDL particle to patient.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and different search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBM

Robert B. Mondesi
Group 1653
Patent Examiner
10-18-04

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653